Complete Summary

GUIDELINE TITLE

Standards of medical care in diabetes. VII. Diabetes care in specific populations.

BIBLIOGRAPHIC SOURCE(S)

American Diabetes Association (ADA). Standards of medical care in diabetes. VII. Diabetes care in specific populations. Diabetes Care 2008 Jan;31(Suppl 1):S33-7.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Diabetes Association (ADA). Standards of medical care in diabetes. VII. Diabetes care in specific populations. Diabetes Care 2007 Jan;30(Suppl 1):S24-7.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Type 1 and type 2 diabetes
- Chronic complications of diabetes, including nephropathy, hypertension, dyslipidemia, retinopathy, celiac disease, and hypothyroidism

GUIDELINE CATEGORY

Evaluation
Management
Prevention

Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Geriatrics
Internal Medicine
Nephrology
Nutrition
Obstetrics and Gynecology
Ophthalmology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Nurses
Physician Assistants
Physicians
Social Workers

GUIDELINE OBJECTIVE(S)

- To provide recommendations for diabetes care in specific populations with respect to:
    - Screening and treating complications in children and adolescents with type 1 or type 2 diabetes mellitus
    - Preconception care in women
    - Management of diabetes in older individuals
- To provide clinicians, patients, researchers, payers, and other interested individuals with the components of diabetes care, treatment goals, and tools to evaluate the quality of care

TARGET POPULATION

- Children and adolescents with type 1 diabetes mellitus
- Children and adolescents with type 2 diabetes mellitus (no specific recommendations provided)
- Women of child-bearing age with diabetes
- Older individuals (>65 years of age)

INTERVENTIONS AND PRACTICES CONSIDERED

Screening for Complications in Children and Adolescents with Type 1 Diabetes Mellitus

1. Screening for microalbuminuria with a random spot urine sample for urine microalbumin-to-creatinine ratio
2. Screening for dyslipidemia (fasting lipid profile)
3. Screening for retinopathy (ophthalmologic examination)
4. Screening for celiac disease using tissue transglutaminase antibodies or an anti-endomysial antibody
5. Screening for thyroid peroxidase and thyroglobulin antibodies and measurement of thyroid-stimulating hormone (TSH) concentrations

Management/Treatment of Diabetes Complications in Children and Adolescents

1. Optimizing glucose control
2. Angiotensin-converting enzyme (ACE) inhibitor
3. Lifestyle interventions
    - Dietary interventions, including gluten-free diet for celiac disease
    - Dietary interventions for weight control
    - Exercise
4. Medical nutrition therapy (MNT) aimed at decreased intake of saturated fats (Step 2 American Heart Association diet)
5. Anti-hypertensive agents
6. Lipid-lowering agents (statin therapy)
7. Annual monitoring and follow-up exams
8. Referral to specialists, as needed

Preconception Care

1. Attainment of target A1C levels before conception
2. Patient education/family planning
3. Preconception evaluation and treatment of diabetic retinopathy, nephropathy, neuropathy, and cardiovascular disease
4. Discontinuation of drugs contraindicated in pregnancy

Management of Diabetes in Older Individuals

1. Individualized screening for diabetes complications
2. Consideration of special needs of older individuals, as well as the heterogeneity of the older population, in relation to treatment goals, including glycemic control, blood pressure, and lipid control
3. Treatment using goals for younger adults, as appropriate
4. Multidisciplinary interventions, including patient education

MAJOR OUTCOMES CONSIDERED

- Risk and rate of congenital malformations
- Risk and rate of early pregnancy loss
- Blood glucose levels
- Blood pressure levels

- Lipid levels
- Patient adherence
- Morbidity and mortality

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

American Diabetes Association's Evidence Grading System for Clinical Practice Recommendations

A

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis
- Compelling non-experimental evidence (i.e., "all or none" rule developed by the Center for Evidence Based Medicine at Oxford*)

Supportive evidence from well-conducted randomized, controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

**Either all patients died before therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.*

B

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

C

Supportive evidence from poorly controlled or uncontrolled studies, including:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

E

Expert consensus or clinical experience

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations have been assigned ratings of A, B or C, depending on the quality of evidence (see "Rating Scheme for the Strength of the Evidence"). Expert opinion (E) is a separate category for recommendations in which there is as yet no evidence from clinical trials, in which clinical trials may be impractical, or in which there is conflicting evidence. Recommendations with an "A" rating are

based on large, well-designed clinical trials or well done meta-analyses. Generally, these recommendations have the best chance of improving outcomes when applied to the population to which they are appropriate. Recommendations with lower levels of evidence may be equally important but are not as well supported.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The recommendations were reviewed and approved in October 2007 by the Professional Practice Committee and, subsequently, by the Executive Committee of the Board of Directors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The evidence grading system for clinical practice recommendations (A through C, E) is defined at the end of the "Major Recommendations" field.

Children and Adolescents

Type 1 Diabetes

Ideally, the care of a child or adolescent with type 1 diabetes should be provided by a multidisciplinary team of specialists trained in the care of children with pediatric diabetes. At the very least, education of the child and family should be provided by health care providers trained and experienced in childhood diabetes and sensitive to the challenges posed by diabetes in this age-group. At the time of initial diagnosis, it is essential that diabetes education is provided in a timely fashion, with the expectation that the balance between adult supervision and self-care should be defined by, and will evolve according to, physical, psychological, and emotional maturity. Medical nutrition therapy (MNT) should be provided at diagnosis, and at least annually thereafter, by an individual experienced with the nutritional needs of the growing child and the behavioral issues that have an impact on adolescent diets.

Glycemic Control

- Consider age when setting glycemic goals in children and adolescents with type 1 diabetes, with less stringent goals for younger children. (E)

Plasma Blood Glucose and A1C Goals for Type 1 Diabetes by Age Group

	Plasma Blood Glucose Goal Range (mg/dL)			
Values by Age (years)	**Before Meals**	**Bedtime/Overnight**	**A1C (%)**	**Rationale**
Toddlers and preschoolers (0 to 6 years)	100 to 180	110 to 200	<8.5% (but >7.5%)	High risk and vulnerability to hypoglycemia
School age (6 to 12 years)	90 to 180	100 to 180	<8%	Risks of hypoglycemia and relatively low risk of complications prior to puberty
Adolescents and young adults (13 to 19 years)	90 to 130	90 to 150	<7.5%	• Risk of severe hypoglycemia • Developmental and psychological issues • A lower goal (<7.0%) is reasonable if it can be achieved without excessive hypoglycemia
Key concepts in setting glycemic goals: • Goals should be individualized and lower goals may be reasonable based on benefit-risk assessment. • Blood glucose goals should be higher than those listed above in children with frequent hypoglycemia or hypoglycemia unawareness. • Postprandial blood glucose values should be measured when there is a discrepancy between pre-prandial blood glucose values and A1C levels.				

Screening and Management of Chronic Complications in Children and Adolescents with Type 1 Diabetes

Nephropathy

- Annual screening for microalbuminuria, with a random spot urine sample for microalbumin-to-creatinine ratio, should be initiated once the child is 10 years of age and has had diabetes for 5 years. (E)
- Confirmed, persistently elevated microalbumin levels on two additional urine specimens should be treated with an angiotensin-converting enzyme (ACE) inhibitor, titrated to normalization of microalbumin excretion if possible. (E)

Hypertension

- Treatment of high-normal blood pressure (systolic or diastolic blood pressure consistently above the 90th percentile for age, sex, and height) should include dietary intervention and exercise, aimed at weight control and increased physical activity, if appropriate. If target blood pressure is not reached within 3 to 6 months of lifestyle intervention, pharmacologic treatment should be initiated. (E)
- Pharmacologic treatment of hypertension (systolic or diastolic blood pressure consistently above the 95th percentile for age, sex, and height or consistently greater than 130/80 mmHg, if 95% exceeds that value) should be initiated as soon as the diagnosis is confirmed. (E)
- ACE inhibitors should be considered for the initial treatment of hypertension. (E)

Dyslipidemia

Screening

- If there is a family history of hypercholesterolemia (total cholesterol >240 mg/dL) or a cardiovascular event before age 55 years, or if family history is unknown, then a fasting lipid profile should be performed on children >2 years of age soon after diagnosis (after glucose control has been established). If family history is not of concern, then the first lipid screening should be performed at puberty (≥10 years). All children diagnosed with diabetes at or after puberty should have a fasting lipid profile performed soon after diagnosis (after glucose control has been established). (E)
- For both age groups, if lipids are abnormal, annual monitoring is recommended. If low-density lipoprotein (LDL) cholesterol values are within the accepted risk levels (<100 mg/dL [2.6 mmol/L]), a lipid profile should be repeated every 5 years. (E)

Treatment

- Initial therapy should consist of optimization of glucose control and MNT using a Step 2 American Heart Association diet aimed at a decrease in the amount of saturated fat in the diet. (E)
- After the age of 10, the addition of a statin is recommended in patients who, after MNT and lifestyle changes, have LDL cholesterol >160 mg/dL (4.1 mmol/L) or have LDL cholesterol >130 mg/dL (3.4 mmol/L) and one or more cardiovascular disease (CVD) risk factors. (E)
- The goal of therapy is an LDL value <100 mg/dL (2.6 mmol/L). (E)

Retinopathy

- The first ophthalmologic examination should be obtained once the child is ≥10 years of age and has had diabetes for 3 to 5 years. (E)
- After the initial examination, annual routine follow-up is generally recommended. Less frequent examinations may be acceptable on the advice of an eye care professional. (E)

Celiac Disease

- Patients with type 1 diabetes who become symptomatic for celiac disease should be tested by measuring tissue transglutaminase or anti-endomysial antibodies, with documentation of normal serum immunoglobulin A (IgA) levels. (E)
- Children with positive antibodies should be referred to a gastroenterologist for evaluation. (E)
- Children with confirmed celiac disease should have consultation with a dietitian and placed on a gluten-free diet. (E)

Hypothyroidism

- Patients with type 1 diabetes should be screened for thyroid peroxidase and thyroglobulin antibodies at diagnosis. (E)
- Thyroid-stimulating hormone (TSH) concentrations should be measured after metabolic control has been established. If normal, they should be rechecked every 1 to 2 years, or if the patient develops symptoms of thyroid dysfunction, thyromegaly, or an abnormal growth rate. Free T4 should be measured if TSH is abnormal. (E)

Type 2 Diabetes

Distinction between type 1 and type 2 diabetes in children can be difficult, since autoantigens and ketosis may be present in a substantial number of patients with features of type 2 diabetes (including obesity and acanthosis nigricans). Such a distinction at the time of diagnosis is critical since treatment regimens, educational approaches, and dietary counsel will differ markedly between the two diagnoses. Because type 2 diabetes has a significant incidence of hypertension, dyslipidemia, and microalbuminuria at diagnosis, it is recommended that screening for the comorbidities and complications of diabetes, including fasting lipid profile, microalbuminuria assessment, and dilated eye examinations, begin at the time of diagnosis. The American Diabetes Association (ADA) consensus statement provides guidance on the prevention, screening, and treatment of type 2 diabetes and its comorbidities in young people.

Preconception Care

- A1C levels should be normal or as close to normal as possible (<7%) in an individual patient before conception is attempted. (B)
- All women with diabetes and childbearing potential should be educated about the need for good glucose control before pregnancy and should participate in family planning. (E)
- Women with diabetes who are contemplating pregnancy should be evaluated and, if indicated, treated for diabetic retinopathy, nephropathy, neuropathy, and cardiovascular disease. (E)
- Medications used by such women should be evaluated before conception, since drugs commonly used to treat diabetes and its complications may be contraindicated or not recommended in pregnancy, including statins, ACE inhibitors, angiotensin receptor blockers (ARBs), and most noninsulin therapies. (E)

Older Adults

- Older adults who are functional, cognitively intact, and have significant life expectancy should receive diabetes treatment using goals developed for younger adults. (E)
- Glycemic goals for older adults who do not meet the above criteria may be relaxed using individual criteria, but hyperglycemia leading to symptoms or risk of acute hyperglycemic complications should be avoided in all patients. (E)
- Other cardiovascular risk factors should be treated in older adults with consideration of the timeframe of benefit and the individual patient. Treatment of hypertension is indicated in virtually all older adults, and lipid and aspirin therapy may benefit those with life expectancy at least equal to the timeframe of primary or secondary prevention trials. (E)
- Screening for diabetic complications should be individualized in older adults, but particular attention should be paid to complications that would lead to functional impairment. (E)

Definitions:

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- Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

E

Expert consensus or clinical experience

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate detection and management of diabetes and its complications in specific populations
- Preconception care of diabetes appears to reduce the risk of congenital malformations

POTENTIAL HARMS

- **Considerations for diabetic women of childbearing age**: Among the oral antidiabetic agents, metformin and acarbose are classified as category B and all others as category C; potential risks and benefits of oral antidiabetic agents in the preconception period must be carefully weighed, recognizing that data are insufficient to establish the safety of these agents in pregnancy.
- **Considerations for older individuals**: Special care is required in prescribing and monitoring pharmacologic therapy in older adults. Metformin is often contraindicated because of renal insufficiency or significant heart failure. Sulfonylureas, other insulin secretagogues, and insulin can cause hypoglycemia. Insulin use requires that patient or caregivers have good visual and motor skills and cognitive ability. Drugs should be started at the lowest

dose and titrated up gradually until targets are reached or side effects develop.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Among the drugs commonly used in the treatment of patients with diabetes, a number may be relatively or absolutely contraindicated during pregnancy. Statins are category X (contraindicated for use in pregnancy) and should be discontinued before conception, as should angiotensin-converting enzyme (ACE) inhibitors. Angiotensin receptor blockers (ARBs) are category C (risk cannot be ruled out) in the first trimester, but category D (positive evidence of risk) in later pregnancy, and should generally be discontinued before pregnancy.
- Thiazolidinediones (TZDs) can cause fluid retention, which may exacerbate or lead to heart failure. They are contraindicated in patients with congestive heart failure (CHF) (New York Heart Association class III and IV), and if used at all should be used very cautiously in those with, or at risk for, milder degrees of CHF.
- See also "Potential Harms" field above for information on metformin use in older individuals.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Evidence is only one component of clinical decision-making. Clinicians care for patients, not populations; guidelines must always be interpreted with the needs of the individual patient in mind. Individual circumstances, such as comorbid and coexisting diseases, age, education, disability, and, above all, patient's values and preferences, must also be considered and may lead to different treatment targets and strategies. Also, conventional evidence hierarchies, such as the one adapted by American Diabetes Association, may miss some nuances that are important in diabetes care. For example, while there is excellent evidence from clinical trials supporting the importance of achieving glycemic control, the optimal way to achieve this result is less clear. It is difficult to assess each component of such a complex intervention.
- While individual preferences, comorbidities, and other patient factors may require modification of goals, targets that are desirable for most patients with diabetes are provided. These standards are not intended to preclude more extensive evaluation and management of the patient by other specialists as needed.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

In recent years, numerous health care organizations, ranging from large health care systems such as the U.S. Veteran's Administration to small private practices

have implemented strategies to improve diabetes care. Successful programs have published results showing improvement in process measures such as measurement of A1C, lipids, and blood pressure. Successful interventions have been focused at the level of health care professionals, delivery systems, and patients. Features of successful programs reported in the literature include:

- Improving health care professional education regarding the standards of care through formal and informal education programs.
- Delivery of diabetes self-management education (DSME), which has been shown to increase adherence to standard of care.
- Adoption of practice guidelines, with participation of health care professionals in the process. Guidelines should be readily accessible at the point of service, such as on patient charts, in examining rooms, in "wallet or pocket cards," on personal digital assistants (PDAs), or on office computer systems. Guidelines should begin with a summary of their major recommendations instructing health care professionals what to do and how to do it.
- Use of checklists that mirror guidelines have been successful at improving adherence to standards of care.
- Systems changes, such as provision of automated reminders to health care professionals and patients, reporting of process and outcome data to providers, and especially identification of patients at risk because of failure to achieve target values or a lack of reported values.
- Quality improvement programs combining Continuous Quality Improvement (CQI) or other cycles of analysis and intervention with provider performance data.
- Practice changes, such as clustering of dedicated diabetes visits into specific times within a primary care practice schedule and/or visits with multiple health care professionals on a single day and group visits.
- Tracking systems either with an electronic medical record or patient registry have been helpful at increasing adherence to standards of care by prospectively identifying those requiring assessments and/or treatment modifications. They likely could have greater efficacy if they suggested specific therapeutic interventions to be considered for a particular patient at a particular point in time.
- A variety of non-automated systems, such as mailing reminders to patients, chart stickers, and flow sheets, have been useful to prompt both providers and patients.
- Availability of case or (preferably) care management services, usually by a nurse. Nurses, pharmacists, and other non-physician health care professionals using detailed algorithms working under the supervision of physicians and/or nurse education calls have also been helpful. Similarly dietitians using medical nutrition therapy (MNT) guidelines have been demonstrated to improve glycemic control.
- Availability and involvement of expert consultants, such as endocrinologists and diabetes educators.

Evidence suggests that these individual initiatives work best when provided as components of a multifactorial intervention. Therefore, it is difficult to assess the contribution of each component; however, it is clear that optimal diabetes management requires an organized, systematic approach and involvement of a coordinated team of health care professionals.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Diabetes Association (ADA). Standards of medical care in diabetes. VII. Diabetes care in specific populations. Diabetes Care 2008 Jan;31(Suppl 1):S33-7.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 (revised 2008 Jan)

GUIDELINE DEVELOPER(S)

American Diabetes Association - Professional Association

SOURCE(S) OF FUNDING

The American Diabetes Association (ADA) received an unrestricted educational grant from LifeScan, Inc., a Johnson and Johnson Company, to support publication of the 2008 Diabetes Care Supplement.

GUIDELINE COMMITTEE

Professional Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Irl Hirsch, MD, Chair; Martin Abrahamson, MD; Andrew Ahmann, MD; Lawrence Blonde, MD; Silvio Inzucchi, MD; Mary T. Korytkowski, MN, MD, MSN; Melinda Maryniuk, MEd, RD, CDE; Elizabeth Mayer-Davis, MS, PhD, RD; Janet H. Silverstein, MD; Robert Toto, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American Diabetes Association (ADA). Standards of medical care in diabetes. VII. Diabetes care in specific populations. Diabetes Care 2007 Jan;30(Suppl 1):S24-7.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Diabetes Association (ADA) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Introduction. Diabetes Care 31:S1-S2, 2008.
- Summary of revisions for the 2008 clinical practice recommendations. Diabetes Care 31:S3-S4, 2008.
- Executive summary: standards of medical care in diabetes. Diabetes Care 31:S5-S11, 2008.
- Strategies for improving diabetes care. Diabetes Care 31:S44, 2008.

Electronic copies: Available from the American Diabetes Association (ADA) Web site.

The following are also available:

- Diagnosis and classification of diabetes mellitus. Diabetes Care 2008 Jan; 31 Suppl 1:S55-60. Electronic copies: Available from the American Diabetes Association (ADA) Web site.
- 2008 clinical practice recommendations standards of care. Personal digital assistant (PDA) download. Available from the American Diabetes Association (ADA) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on April 2, 2001. The information was verified by the guideline developer on August 24, 2001. This summary was updated by ECRI on January 29, 2002, April 21, 2003, March 23, 2004, July 1, 2005, and March 17, 2006 and April 26, 2007. This summary was updated most recently by ECRI Institute on March 31, 2008. The updated information was verified by the guideline developer on May 15, 2008.

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DISCLAIMER

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